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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,911	12/18/2001	Kit Yeng Lim	SBI-100	4817
45488	7590	03/18/2005		
WILLIAMS, MORGAN & AMERSON, P.C./ZIMMER 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			EXAMINER RAMANA, ANURADHA	
			ART UNIT 3732	PAPER NUMBER
DATE MAILED: 03/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 10/023,911	Applicant(s) LIM ET AL.	
	Examiner Anu Ramana	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-17, 19-28, 30-33, 35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-17, 19-28, 30-33, 35 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/18/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 20, 2004 has been entered.

Response to Amendment

The amendment filed on December 20, 2004 has been entered. Applicants' should refer to 37 CFR 1.121(d) for the manner of making amendments. It is noted that the no claim text should be presented for canceled claims (claims 9, 18 and 29).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 6, 10-11, 13-14, 16, 19-20, 22-25 and 30-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Michelson (US 6,537,320).

Michelson discloses an implant or plug 20 made of a bioresorbable or "biodegradable" material such as polylactone ("polymer") having a hollow portion or "bore" 42 containing bone growth inducing or promoting material and fins or "threads" (36, 36') on its outer surface wherein the plug is sealed at one end by a cap or "sealing

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member" 46 having a slot to engage a driver or tool for inserting and rotating implant 20 into disc space (Figures 1, 2A, 2E, 16A and 16B, col. 11, lines 16-26, col. 12, lines 30-51, col. 13, lines 24-60, col. 15, lines 59-67 and col. 16, lines 1-31).

Michelson also discloses a plurality of openings or "apertures" 38, 38' on the upper and lower walls 30, 30', passing through the body and in communication with bore 42 (col. 12, lines 62-67 and col. 13, lines 1-23.)

The method steps of claims 19-20, 22-25 and 30-33 are inherently performed during normal use of the Michelson implant for the purpose of sealing an intervertebral defect (Figures 3A and 3B, col. 18, lines 51-67 and col. 19, lines 1-31).

Claims 1-2, 6, 10-11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Boyer, II et al. (US 6,767,369).

Boyer, II et al. disclose a plug 280 for filling vacancies or defects in bone tissue having an external thread 286, a cap and apertures 284 wherein the plug may be formed using resorbable or "biodegradable material" and filled with bone growth materials (Fig. 3N, col. 3, lines 66-67, col. 4, lines 1-56, col. 8, lines 31-59, col. 9, lines 8-65, col. 10, lines 47-67, col. 11, lines 1-67 and col. 12, lines 1-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7-8, 12, 15, 17, 21, 26-28, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (US 6,537,320) in view of Boyce et al. (US 6,294,187).

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Regarding claims 5, 15 and 26, Michelson does not disclose specific types of biodegradable polymers.

Regarding claims 7-8, 12, 17, 21, 27 and 28, Michelson does not disclose specific types of bone growth materials.

Boyce et al. teach biodegradable polymers such as polylactic-co-glycolic acid, polycaprolactone, polycyanoacrylates etc. (col. 8, lines 23-40).

Boyce et al. also teach the use of bioactive substances such as antibiotics, living cells, peptides, growth factors such as TGF-beta, bone morphogenetic proteins (BMPs), angiogenic agents etc. (col. 9, lines 31-67) in an implant.

Further, regarding claims 35 and 37, Boyce et al. teach shaping an osteoimplant to assume a determined configuration to custom fit a bone repair site with precision (col. 14, lines 6-50).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the Michelson implant of a biodegradable polymer, as taught by Boyce et al. to make the Michelson implant biodegradable. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bioactive substances taught by Boyce et al. in the Michelson implant to promote bone growth and to have shaped the Michelson implant to custom fit a repair site.

The method steps of claims 21, 26, 27, 28, 35 and 37 are performed during normal use of the Michelson-Boyce et al. implant for sealing an intervertebral defect.

Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer, II et al. (US 6,767,369), as applied to claim 1, in view of Michelson (US 6,537,320).

Boyer, II et al. disclose all elements of the claimed invention except for a cap with a slot for mating with a tool.

Michelson teaches a cap 46 for an implant wherein the cap may be configured to engage a driver or "tool" for inserting and rotating the implant (Figures 1, 2A and 2E and col. 13, lines 54-57).

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Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a cap with a slot, as taught by Michelson, in the Boyer, II et al. plug, so that the plug may be inserted or rotated with a driver or tool.

Claims 4-5, 7-8, 12, 14, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer, II et al. (US 6,767,369), as applied to claim 1, in view of Boyce et al. (US 6,294,187).

Regarding claims 4, 5 and 15, Boyer, II et al. disclose all elements of the claimed invention except for resorbable materials such as biodegradable polymers.

Regarding claims 7-8, 12 14, 15 and 17, Boyer, II et al. do not disclose specific types of bone growth materials.

Boyce et al. teach biodegradable polymers such as polylactic-co-glycolic acid, polycaprolactone, polycyanoacrylates etc. (col. 8, lines 23-40).

Boyce et al. also teach the use of bioactive substances such as antibiotics, living cells, peptides, growth factors such as TGF-beta, bone morphogenetic proteins (BMPs), angiogenic agents etc. to accelerate the ingrowth of new bone tissue in an implant (col. 9, lines 31-67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to have made the Boyer, II et al. implant of a biodegradable polymer, as taught by Boyce et al. to make the Boyer, II et al. implant biodegradable. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the bioactive substances taught by Boyce et al. in the Boyer, II et al. implant to promote bone growth.

Claims 19-23, 25-28, 30-33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (US 6,224,630) in view of Boyer, II et al. (US 6,767,369).

Bao et al. disclose sealing a defect in an intervertebral disc such as an annular tear using a plug (Figures 1-2, col. 1, lines 4-7, col. 2, lines 58-67 and col. 3, lines 1-22).

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Bao et al. disclose all elements of the claimed invention except for the use of a biodegradable plug having a thread on its outer surface and filled with a growth promoting matrix.

Boyer, II et al. teach a type of biodegradable plug for filling bony defects having a threaded outer surface and filled with a growth promoting matrix (Fig. 3N, col. 3, lines 66-67, col. 4, lines 1-56, col. 8, lines 31-59, col. 9, lines 8-65, col. 10, lines 47-67, col. 11, lines 1-67 and col. 12, lines 1-45).

It would have been obvious to one of ordinary skill in the art to substitute a plug as, for example, taught by the Boyer, II et al. reference for the plug of the Bao et al. wherein so doing would amount to mere substitution of one functionally equivalent plug for another within the same art and the selection of any of these plugs would work equally well in the claimed method.

Regarding claims 25-26, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the plug of the combination of Bao et al. and Boyer, II et al. of a resorbable material such as biodegradable polymers, for e.g., poly(L-lactides), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein resorbability, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 21, 27 and 28, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected growth promoting compounds such as growth factors, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein aiding bone ingrowth, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Regarding claims 32 and 33, Bao et al. disclose that placement of a plug can be made utilizing a variety of surgical instruments such as a cannula or catheter (col. 13, lines 38-47 and col. 14, lines 45-65).

The claimed method steps are rendered obvious by the above discussion.

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Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR 
March 13, 2005


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
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